REMARKS

Claims 1-31 are pending and subject to restriction in the above-identified application.

Applicants request consideration and entry into the record of the following amendments and remarks.

Restriction Requirement

In the June 7, 2006 Office Action, the Examiner has required restriction of claims 1-31 of the present invention to one of eleven groups, identified as Groups I to IX:

Group I: Claims 1-5 and 20, drawn to the compound carvedilol dihydrogen phosphate hemihydrate and a pharmaceutical composition, which comprises carvedilol dihydrogen phosphate hemihydrate

Group II: Claims 6-10 and 21, drawn to the compound carvedilol dihydrogen phosphate dihydrate and a pharmaceutical composition, which comprises carvedilol dihydrogen phosphate dihydrate.

Group III: Claims 11-13, drawn to the compound carvedilol dihydrogen phosphate methanol solvate.

Group IV: Claims 14-16 and 22, drawn to a compound carvedilol dihydrogen phosphate and a pharmaceutical composition, which comprises carvedilol dihydrogen phosphate.

Group V: Claims 17-19 and 23, drawn to a compound carvedilol hydrogen phosphate and a pharmaceutical composition, which comprises carvedilol hydrogen phosphate.

Group VI: Claims 24 and 28, drawn to a method of treating a disease, which comprises administering a compound of claim 1, and a method of treating a disease, which comprises administering a pharmaceutical composition according to claim 20.

Group VII: Claims 25 and 29, drawn to a method of treating a disease, which comprises administering a compound of claim 6, and a method of treating a disease, which comprises administering a pharmaceutical composition according to claim 21.

Group VIII: Claims 26 and 30, drawn to a method of treating a disease, which comprises administering a compound of claim 14, and a method of treating a disease, which comprises administering a pharmaceutical composition according to claim 22.

Group IX: Claims 27 and 31, drawn to a method of treating a disease, which comprises administering a compound of claim 17, and a method of treating a disease, which comprises administering a pharmaceutical composition according to claim 23.

In response to the restriction requirement, applicants provisionally elect, with traverse, to prosecute:

Group I: Claims 1-5 and 20, drawn to the compound carvedilol dihydrogen phosphate hemihydrate and a pharmaceutical composition, which comprises carvedilol dihydrogen phosphate hemihydrate

The Examiner indicated a restriction was required under PCT Rules 13.1 and 13.2, as the claimed inventions of Groups I-IX do not relate to a single general inventive concept for lacking the same or corresponding special technical features that define a contribution over the prior art as exemplified by U.S. 4,053,067. The Examiner further states that while:

> "compounds of Group I-IX of claimed invention are drawn to the common structural moiety carvedilol", "claims 1-31 are not so linked as to form a single general concept and there is lack of unity of invention. The variables vary extensively and when take as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on the examination of the claimed subject matter."

Applicants respectfully traverse for the following reasons:

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general concept (i.e., "requirement of unity of invention").

PCT Rule 13.2 states that unity of invention shall be fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art".

M.P.E.P. Sections §§§ 802.01, 802.02 and 803 state that:

> "Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and §808.01) or distinct (MPEP §806.05- §>806.05(j))."

> "Inventions are "independent" (i.e., not dependent) if there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. (see also MPEP § 806.06 and § 808.01.)"

"Inventions are distinct when "two or more inventions are related . . . but are capable of separate manufacture, use or sale as claimed and are patentably distinct over each other".

"Under M.P.E.P. 808.02, "the Examiner in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:

(A) **Separate classification thereof**: . .
(B) **A separate status in the art when they are classifiable together**. . ..
(C) **A different field of search . . .**

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions."

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

In light of the above, applicants respectfully maintain that Examiner has not provided sufficient evidence or reasons to establish why restriction is proper or to show why a serious search burden would be imposed upon examination of the claimed invention for the following reasons.

the reference cited to break unity of invention, U.S. 4,053,067 to Katz et al. is directed to a "Fuel Transfer System to a Nuclear Reactor" and is not related to carvedilol salts, anhydrates or solvates of the above-identified application;

the Examiner stated that "compounds of Group I-IX of claimed invention are drawn to the common structural moiety carvedilol", and

no assignment of individual class and subclasses designations from the U.S. Classification Manual to the Groups I-IX, respectively.

Applicants submit that the same prior art search will apply to the separate and distinct inventions of the present application such that the above-identified restriction requirement is improper.

In accordance with U.S. Patent Law, there are no reasons that exist for dividing among independent or related inventions of the present invention such that search and examination of all the claims in an application can be made without serious burden, even though they include claims to independent or distinct inventions. In particular, as the Examiner has noted that "compounds of Group I-IX of claimed invention are drawn to the

common structural moiety carvedilol", each of the distinct and different carvedilol salt, solvate or anhydrate forms claimed in the present application would be the subject of a search in the same class and subclass of the U.S. Classification System. Moreover, the carvedilol salt, solvate and/or anhydrate forms of the present invention are so connected as to have arisen from a singular research effort with common shared properties as the aforementioned compound forms are used for treatment of specific cardiovascular diseases, i.e., hypertension, congestive heart failure and angina.

In the instant case, compelling applicants to pursue each of the carvedilol salt, solvate and/or anhydrate forms claimed in the present invention in five separate applications and corresponding pharmaceutical compositions and treatment methods in four additional separate applications only will serve to place additional efforts and burden on the U.S. Patent Office and applicants.

Moreover, applicants note that lack of unity under PCT rules 13.1 and 13.2 were not held during either PCT examination in identical corresponding applications to the present inventions. Claims of the present invention do not lack unity under PCT Rule 13.1 and 13.2, but have a "significant structural element" qualifying as a "special technical feature" that defines a contribution over the prior art. PCT Rule 13.1 includes within the definition of unity of invention "a group of inventions so linked as to form a general inventive concept".

Patentably distinct inventions do not lack unity of invention as long as they derive from the same inventive concept. What is required for a holding of lack of unity is that the inventions be truly "independent". This is the standard for lack of unity applied by the court in *In re Harnish*, 206 USPQ 300, 306 (CCPA 1980) ("unity of invention" ... appl[ies] where *unrelated* inventions are involved") (emphasis supplied). Independent, as defined in MPEP § 802.01, "means that there is no disclosed relationships between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect".

For the record, as elected subject matter for examination on the merits is directed to a product (i.e., compound), applicants also reserve the right to request rejoinder of commensurate in scope non-elected subject matter or inventions (i.e., such as corresponding treatment methods, pharmaceutical compositions and processes) upon the determination of allowable subject matter (*In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996); also see MPEP § 821.04 (b)).

In light of the foregoing, applicants reserve the right to file non-elected inventions as the subject of future applications, which may derive priority from the present application, without prejudice.

Therefore, applicants respectfully request that the Examiner withdraw the above-identified restriction requirement.

CONCLUSION

In view of the above amendments and remarks, applicants believe that the claims of the present application are in condition for allowance, which is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

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